Hans Boehringer et al. Application No.: 08/812,616 Page 2 10. (sbp member), comprising: flows along the flow path;

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(Amended) [The] A method of [claim 1,] visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample

observing a pattern of label that accumulates at the one or more capture zones;

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the second sbp member is an antibody against a complex formed between the analyte and the first sbp member.

15. (Amended) [The] A method of [claim 1,] visually quantifying an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of label that accumulates at the one or more capture zones;

and

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correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

(Amended) [The] A method of [claim 18,] determining an amount of 23. an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

contacting the sample with the sample receiving zone, whereby the sample flows along the flow path;

observing a pattern of labeled first sbp member that accumulates at the one or more capture zones; and

correlating a pattern of label accumulated in the one or more capture zones to the amount of analyte in the sample;

wherein the labeled first sbp member includes a visually detectable label;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

In claim 53, lines 9-10, after the words "complementary to", delete the words "or analogous to".

In claims 56-57, change the claim dependencies from "claim 55" to -claim 53--.

Hans Boehringer et al. Application No.: 08/812,616 Page 4 In claim 58, change the dependency from "claim 59" to --claim 57--. 1 In claims 59-61, change the dependencies from "claim 55" to --claim 53--. 1 62. (Amended) [The] A device [of claim 55,] for determining an amount of 1 an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp 2 3 member), comprising a lateral flow matrix which defines a flow path and which comprises in 4 series: 5 a sample receiving zone; 6 a labeling zone; and one or more serially oriented capture zones; 7 wherein the labeling zone comprises a diffusively bound labeled first sbp 8 9 member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the 10 second sbp member being complementary to the analyte; 11 wherein the second sbp member is an antibody against a complex formed between the analyte 12 and the first sbp member. 13 In claim 63, change the dependency from "claim 55" to --claim 53--. 1 1 In claim 65, change the dependency from "claim 55" to --claim 53--. 1 In claim 66, change the dependency from "claim 67" to --claim 65--. In claims 67-68 and 70, change the claim dependencies from "claim 55" to --1 2 claim 53--. (Amended) [The] A device [of claim 55,] for determining an amount of 1 69. an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp 2 3 member), comprising a lateral flow matrix which defines a flow path and which comprises in series: 4

a sample receiving zone;

a labeling zone; and

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one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to or analogous to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being complementary to the analyte;

wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

In claim 71, change the dependency from "claim 72" to --claim 70--.

In claims 73 and 74, change the claim dependencies from "claim 74" to --claim

In claim 75, change the claim dependency from "claim 76" to --claim 74--.

In claims 76-78, and 80, change the claim dependencies from "claim 74" to -claim 72--.

(Amended) [The] A device [of claim 74,] for determining an amount of 79. an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte;

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wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

In claim 81, change the claim dependency from "claim 82" to --claim 80--.

120. (Amended) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of [any one of] claim[s 55,] 53 [74, 84, 98 or 110], a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

Please add new claims 121-125 as follows:

--121. (New) A kit for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the kit comprising the device of claim 74, a chart for correlating an observed accumulation of label at the one or more capture zones, to a concentration of analyte in a sample applied to the sample receiving zone, and instructions for using the device.

- 122. (New) The device of claim 53, wherein the first sbp member is a ligand and the second sbp member is a receptor complementary to the ligand.--
- 123. (New) The device of claim 121 wherein the ligand is a hapten and the receptor is a complement to the hapten.
- sample, wherein the analyte is a member of a specific binding pair (sbp member), comprising:

  providing a lateral flow matrix which defines a flow path and which comprises in series, a sample receiving zone, a labeling zone, and one or more serially oriented capture zones, wherein the labeling zone comprises a diffusively bound labeled first sbp member that

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